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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Parkin *et al.*

Serial No.: 09/591,899

Filed: June 12, 2000

For: MEANS AND METHODS FOR MONITORING PROTEASE INHIBITOR ANTIRETROVIRAL THERAPY AND GUIDING THERAPEUTIC DECISIONS IN THE TREATMENT OF HIV/AIDS

Confirmation No.: 3775

Group Art Unit: 1648

Examiner: S. Foley

Attorney Docket No.: 11068-035-999

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:

1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.

1b. A legible copy of:

☒ Each U.S. patent application publication and U.S. and foreign patent;

☒ Each publication or that portion which caused it to be listed on the PTO-1449;

☐ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;

☐ all other information or portion which caused it to be listed on the PTO-1449.

1c. ☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.

1d. ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.

2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):

☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);

☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;

☐ Before the mailing of the first Office action on the merits;

☒ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.

3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

(Check either Item 3a or 3b)

3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.

3b. ☐ The $180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
☐ enclosed
☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

(Item 3b to be checked if any reference known for more than 3 months)

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The $180.00 fee set forth in 37 C.F.R. §1.17(p) is:
☐ enclosed.
☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

The Certification Statement in Item 5 below is applicable.

5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked)

(Check either Item 5a or 5b)

5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

5b. ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.

5c. ☐ Pursuant to 37 C.F.R. §1.704(d), each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.

6. ☐ This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).

(Check appropriate Items 6a, 6b and/or 6c)

6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently

filed herewith.

6b. ☐ Copies of publications listed on Form PTO-1449 from prior application Serial No. , filed on , of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).

6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. , filed on , and are provided herewith.

7. ☐ This is a Supplemental Information Disclosure Statement. (Check Item 7a)

7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on . A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on .

8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:

(Check Item 8a, 8b, or 8c)

8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.

8b. ☐ set forth in the application.

8c. ☐ enclosed as an attachment hereto.

9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Pennie & Edmonds LLP Deposit Account No. 16-1150.

10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date: December 30, 2003

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LIST OF REFERENCES CITED BY APPLICANT
(Use several sheets if necessary)

ATTY DOCKET NO.	APPLICATION NO
11068-035-999	09/591,899
APPLICANT	
Parkin et al.	
FILING DATE	GROUP
June 12, 2000	1648

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
SF	A01	5,766,842	6/16/98	Melnick et al.			

OTHER REFERENCES *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	A02	Dreyer GB, *et al.*"A Symmetric Inhibitor Binds HIV-I Protease Asymmetrically" *Biochemistry* (1993) 32:937-947
	A03	J. Eron, *et al.*, Preliminary Assessment of 141 W94 in Combination with Other Protease Inhibitors," *5th Conference on Retroviruses and Opportunistic Infections:* (1995) 6
	A04	Hill, A. *et al.* (1998) "Low frequency of genotypic mutations associated with resistance to AZT and 3TC after combination treatment with indinavar," *Int. Conf. AIDS* 12:812, (Abstract No. 6)
	A05	E. E. Kim, (1995) " Crystal Structure of HIV-1 Protease in Complex with VX-478, a Potent and Orally Bioavailable Inhibitor of the Enzyme," *J. Am. Chem. Soc.*, 117: 1181-1182
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	A16	Sarah Palmer, *et al.*, (1999) "Highly Drug-resistant HIV-1 Clinical Isolates Are Cross-resistant to Many Antiretroviral Compounds in Current Clinical Development," *AIDS*, 13: 661-667
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EXAMINER	DATE CONSIDERED
	3/22/4

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with **MPEP 609**; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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SF	A19	Petit SC, *et al.* (1993) "The Specificity of the HIV-1 Protease" *Drug Discov Des* 1:69-83
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	A27	Tisdale, M. *et al.* (1998): "Genotypic and phenotypic analysis of HIV from patients on ZDV/3TC/amprenavir combination therapy," *Int. Conf AIDS* 12:583 (Abstract No. 32312)
SF	A28	Simon P. Tucker, *et al.*, (1998) "Estimate of the Frequency of !Human Immunodeficiency Virus Type 1 Protease Inhibitor Resistance Within Unselected Virus Populations In Vitro," *Antimicrobial Agents and Chemotherapy*, 42: 478-480

EXAMINER	DATE CONSIDERED
Steven Fong	8/22/04

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with **MPEP 609**; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.